IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF NORTH CAROLINA CHARLOTTE DIVISION CIVIL ACTION NO. 3:22-MD-03036-KDB

| IN RE: GARDASIL PRODUCTS LIABILITY LITIGATION |) MDL No. 3036 |
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| | THIS DOCUMENT RELATES TO: |
| |) CASE NO. 3:24-CV-00291, Needham) v. Merck & Co., Inc. et al. |
| | CASE NO. 3:24-CV-00278, Roman v. Merck & Co., Inc. et al. |
| |) (CASE NO. 3:24-CV-00433, Walker v.) Merck & Co., Inc. et al. |
| | CASE NO. 3:23-CV-00729, Nielsen v. Merck & Co., Inc. |

THIS MATTER is before the Court on Defendants' (together "Merck") motions to dismiss the Complaints of Plaintiffs Needham, Roman, Walker and Nielson (Doc. Nos. 141, 144). The Court has carefully considered these motions, the parties' briefs and exhibits and oral argument on the Needham, Roman and Walker motion from those Plaintiffs' counsel and Defendants' counsel on July 18, 2024. In this multi-district litigation ("MDL"), Plaintiffs assert vaccine injury claims against Merck, which are subject to the National Childhood Vaccine Injury

ORDER

¹ Plaintiff Nielson is a *pro se* plaintiff who did not appear at the hearing at which the motion related to the other plaintiffs was argued. Further, Plaintiff Nielson has not responded to Defendants' motion despite the entry and service of a "Roseboro Order" directing him to respond and informing him that if he did not do so it might result in the dismissal of his claims. *See* July 9, 2024 Text Order.

Act ("Vaccine Act" or "Act"), 42 U.S.C. § 300aa-1 et seq. That statute requires a person seeking damages for an alleged vaccine injury to file a timely petition in "Vaccine Court" before she may file a civil action in State or Federal Court. *See* 42 U.S.C. § 300aa-11(a)(2)(A). Plaintiff Nielson did not file a petition in Vaccine Court, and Plaintiffs Needham, Roman and Walker did not file their Vaccine Court petitions within the three year statutory limitations period. Therefore, Merck's motions will be **GRANTED**, and this Court, as directed by the Act, "shall dismiss the action[s]" brought by these Plaintiffs. *See* 42 U.S.C. § 300aa-11(a)(2)(B).

I. FACTS AND PROCEDURAL HISTORY

Since August 2022, this Court has been the forum for a MDL in which nearly two hundred cases asserting vaccine injury claims against Merck have been consolidated. (Doc. No. 2). Each Plaintiff alleges that he or she has suffered harm caused by vaccination with Gardasil, a Human Papillomavirus ("HPV") vaccine which seeks to prevent cervical and other cancers believed to be associated with HPV. Mr. Nielson, Ms. Needham, Ms. Roman, and Ms. Walker directly filed complaints in the MDL alleging Gardasil-related injuries. (*See Needham v. Merck & Co., Inc.*, Case No. 3:24- cv-00291 (W.D.N.C. Mar. 8, 2024), Doc. No. 1 ("Needham Compl."); *Roman v. Merck & Co., Inc.*, Case No. 3:24-cv-00278 (W.D.N.C. Mar. 5, 2024), Doc. No. 1 ("Roman Compl."); *Walker v. Merck & Co., Inc.*, Case No. 3:24-cv-00433, Doc. No. 1 (W.D.N.C. Apr. 29, 2024) ("Walker Compl."); *Nielsen v. Merck & Co., Inc.*, Case No. 3:23-CV-00729 (W.D.N.C. Nov. 2, 2023), Doc. No. 1 ("Nielson Compl.").)

Prior to filing his claims in the MDL, Plaintiff Nielson did not file a claim in the Vaccine Court. Plaintiffs Needham, Roman and Walker did file claims in the Vaccine Court, but their petitions were dismissed as untimely because they did not file their compensation claims within three years of the first symptoms they claimed were related to their Gardasil vaccinations.

Needham v. Sec'y of Health & Hum. Servs., No. 23-630V, 2023 WL 9287882, at *1 (Fed. Cl. Dec. 20, 2023); Roman v. Sec'y of Health & Hum. Servs., No. 23-705V, 2024 WL 470570, at *1 (Fed. Cl. Jan. 5, 2024); Walker v. Sec'y of Health & Hum. Servs., No. 23-1038V, 2024 WL 1281508, at *1 (Fed. Cl. Feb. 29, 2024). According to the dismissal orders:

- Ms. Needham received her last Gardasil vaccination on July 14, 2015, and began to experience symptoms in the fall of 2015. Needham, 2023 WL 9287882, at *1. She did not file a petition in Vaccine Court until May 2, 2023, seven years later. *Id*.
- Ms. Walker received her last Gardasil vaccination on August 14, 2015, began experiencing symptoms, and was diagnosed with chronic fatigue syndrome in November 2016. Walker, 2024 WL 1281508, at *1. She filed her Vaccine Court petition on July 5, 2023, six years later. Id.
- Ms. Roman received her last Gardasil vaccination on September 17, 2009, and began to experience symptoms about a month later. Roman, 2024 WL 470570, at *1. Ms. Roman did not file in Vaccine Court until May 12, 2023, 13 years later. Id.

² In a motion for lack of subject matter jurisdiction, the Court "may consider evidence outside the pleadings without converting the proceeding to one for summary judgment." Richmond,

Fredericksburg & Potomac R. Co. v. United States, 945 F.2d 765, 768 (4th Cir. 1991). In addition, a court may properly take judicial notice of matters in the public record in considering a motion to dismiss. See Philips v. Pitt Cnty. Mem'l Hosp., 572 F.3d 176, 180 (4th Cir. 2009) (citing Hall v. Virginia, 385 F.3d 421, 424 (4th Cir. 2004)); Megaro v. McCollum, 66 F.4th 151, 158 (4th Cir. 2023) (taking judicial notice of a "publicly available" "administrative decision from a body acting in a judicial capacity"). The Vaccine Court decisions on Ms. Needham's, Ms. Roman's, and Ms. Walker's claims have been "made publicly accessible and [are] posted on the United States Court of Federal Claims' website . . . in accordance with the E-Government Act of 2002," and are "available to anyone with access to the internet." Needham, 2023 WL 9287882 at *1 n.1; Roman, 2024 WL 470570, at *1 n.1; Walker, 2024 WL 1281508, at *1 n.1. 2024 WL 1281508, at *1.

Based on these facts, each Plaintiff conceded in Vaccine Court that their claims were facially untimely. *Roman*, 2024 WL 470570, at *2 ("The untimeliness of this filing is acknowledged by Petitioner . . . "); *Needham*, 2023 WL 9287882, at *3 (same); *Walker*, 2024 WL 1281508, at *2 (same). However, they each argued that the three-year limitations period in the Vaccine Act should be equitably tolled. The Vaccine Court disagreed and dismissed their claims as time barred. *Roman*, 2024 WL 470570, at *2–3; *Needham*, 2023 WL 9287882, at *2–3; *Walker*, 2024 WL 1281508, at *2–4.

Ms. Needham, Ms. Roman, and Ms. Walker did not appeal the Vaccine Court's dismissals for untimeliness to the Court of Federal Claims, or to the Court of Appeals for the Federal Circuit. Instead, they each filed elections to pursue civil actions in federal or state court. (*See* Ex. 1, Needham Docket Sheet, Case No. 1:23-VV-00630, Doc. No. 24 (Fed. Cl. Feb. 8, 2024); Ex. 2, Roman Docket Sheet, Case No 1:23-VV-00705, Doc. No. 22 (Fed. Cl. Feb. 8, 2024); Ex. 3, Walker Docket Sheet, Case No. 1:23-VV-01038, Doc. No. 18 (Fed. Cl. Mar. 4, 2024).) All three Plaintiffs then filed their Complaints in the MDL.

II. DISCUSSION

Gardasil is a childhood vaccine covered by the Vaccine Act, which this Court has previously discussed in detail. *See* Doc. Nos. 132, 156. In brief summary, seeking to stabilize the vaccine market and assist putative plaintiffs, Congress established a no-fault compensation program (the "Program") "designed to work faster and with greater ease than the civil tort system." *See Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 228–30 (2011). A "proceeding for compensation" for a vaccine-related injury is initiated by filing a petition for compensation against the Secretary of Health and Human Services in the United States Court of Federal Claims, where a special master makes an informal adjudication of the petition, subject to appeal to that court and the Federal Circuit. *See* 42 U.S.C. § 300aa–11, 12.

If the claimant is satisfied with the court's judgment (either awarding or not awarding compensation), she can accept it; if not, she can elect to file a "civil action" against the vaccine manufacturer in State or Federal court. *See* 42 U.S.C. § 300aa–21(a). However, the Act sets a period of limitations for the bringing of such civil actions. *Id.* 42 U.S.C. § 300aa–11 provides:

(2)(A) "No person may bring a civil action for damages ... unless a petition has been filed, in accordance with section 300aa-16 of this title, for compensation under the Program...

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(B) If a civil action which is barred under subparagraph (A) is filed in a State or Federal Court, the court shall dismiss the action..."

In 42 U.S.C. § 300aa–16 ("Limitations of actions"), the Act requires that a petition for compensation must be filed within 36 months of "the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of [a vaccine-related] injury." 42 U.S.C. § 300aa–16(a)(2).

Therefore, no one may bring "a civil action for damages" against a vaccine manufacturer "for damages arising from a vaccine-related injury" unless she has first timely filed and exhausted a petition for compensation in the U.S. Court of Federal Claims. *See* 42 U.S.C. § 300aa-11(a)(2)(A); *See Goetz v. N. Carolina Dep't of Health & Hum. Servs.*, 203 N.C. App. 421, 431–32, 692 S.E.2d 395, 402 (2010). In *Goetz*, the court explained why a timely petition is a precondition to pursuing a civil action under the statute:

Because plaintiffs failed to exhaust their federal remedies in a timely manner, their subsequent state action should have been dismissed. As explained above, any other construction would allow a claimant to circumvent the federal program by filing outside the federal limitations period but still within the state limitations period. Absent a timeliness requirement, the filing of a federal petition would be a mere technical prerequisite to filing under the state statute. This is directly contrary to Congress' intent. This Court cannot allow a construction of the Federal Vaccine Act that contravenes Congress' stated goal of expediting the presentation and resolution of claims, nor can it allow a construction which renders compliance with that Act's provisions optional.

Id.; see Shalala v. Whitecotton, 514 U.S. 268, 270 (1995); Powers v. Merck & Co., No. 2:17-CV-268, 2018 WL 8899566, at *3 (S.D. Ohio Sept. 13, 2018), aff'd, 773 F. App'x 304 (6th Cir. 2019) ("a party cannot file a civil action against a vaccine manufacturer for a 'vaccine-related injury' unless the party first filed a timely petition [in Vaccine Court] in accordance with the Vaccine Act's requirements."); Blackmon v. Am. Home Prod. Corp., 328 F. Supp. 2d 647, 651 (S.D. Tex. 2004); McDonald v. Lederle Laboratories, 341 N.J.Super. 369, 775 A.2d 528 (2001).

In its motions to dismiss, Merck asks the Court to dismiss the claims of these Plaintiffs because either no petition was filed in Vaccine Court (Nielson) or their petitions were untimely (Needham, Roman and Walker). The publicly available record supports Merck's contention that Nielson did not file a petition, and he has not filed any response to Merck's motion. Therefore, Merck's motion will be granted as to Nielson and his claims dismissed.

Plaintiffs Needham, Roman and Walker oppose Merck's motion. They do not dispute that the Vaccine Act requires that they file a timely petition in Vaccine Court to be permitted to file a civil action in this Court. Instead, as in the Vaccine Court, they argue that their petitions were timely filed because the 36-month limitations period from the onset of their symptoms (which they concede they missed) should be "equitably tolled" based on the difficulty of discovering the connection of their injuries to Gardasil and Merck's alleged concealment of the harm caused by the vaccine. In response, Merck contends that the Court should dismiss their claims based on the Vaccine Court's ruling that the petition was untimely, and, if the Court independently reviews the timeliness of the petitions, find that the Plaintiffs are not entitled to equitable tolling under the circumstances alleged in their Complaints.

The threshold issue before the Court is whether it has the authority and duty to reconsider (and potentially overrule) the Vaccine Court / Court of Federal Claims' decision on the timeliness of these Plaintiffs' Vaccine Court petitions. There is no clear guidance on this issue from any federal circuit court, although the few courts that have ruled on the issue have all supported Defendants' position. See *Powers v. Merck & Co., Inc.*, No. 2:16-cv-699 (S.D. Ohio Jan. 4, 2017) (filed at Doc. No. 145-5) (dismissing civil action "for lack of subject-matter jurisdiction" where Vaccine Court had dismissed underlying claim as untimely); *Hebern v. Am. Cyanamid Co.*, No. A-3063-09T1, 2011 WL 135779, at *5 (N.J. Super. Ct. App. Div. Jan. 13, 2011); *McDonald v. Lederle Lab'ys.*, 775 A.2d 528, 530 (N.J. Super. Ct. App. Div. 2001)). For the reasons discussed below, the Court finds that the decision as to the application of the Vaccine Act's limitations period to petitioners in the Vaccine Court is properly decided by those Special Masters and their reviewing courts, the Court of Federal Claims and the Federal Circuit.

First, while Congress intended for those who timely requested compensation from the Vaccine Court to have the opportunity to elect a civil action following the Vaccine Court process, it did not make the courts that tried those subsequent civil actions a reviewing court for the Vaccine Court's procedural rulings on timeliness, etc. That task was given to the Court of Federal Claims and the Federal Circuit. *See* 42 U.S.C. § 300aa-12(a),(f) ("The United States Court of Federal Claims and the United States Court of Federal Claims special masters shall, in accordance with this section, have jurisdiction over proceedings to determine if a petitioner under section 300aa-

³ Although Plaintiffs did not appeal the Vaccine Court's decision to the Court of Federal Claims, by operation of the statute the Special Master's decision became the judgment of the Court of Federal Claims in the absence of an appeal. *See* 42 U.S.C. § 300aa-12(e)(3).

⁴ Plaintiffs have cited no case in which a court has reversed a decision of the Vaccine Court that a petition was untimely filed and the Court has found none.

11 of this title is entitled to compensation under the Program and the amount of such compensation" / "any petitioner aggrieved by the findings or conclusions of the court may obtain review of the judgment of the court in the United States court of appeals for the Federal Circuit...").

Plaintiffs argue that the Court must decide the application of the Vaccine Act's period of limitations "de novo," citing Shalala v. Whitecotton, 514 U.S. at 270, which used the term in noting a petitioner's right to elect to file a civil action after the conclusion of Vaccine Court proceedings. ("A claimant alleging that more than \$1,000 in damages resulted from a vaccination ... must exhaust the Act's procedures and refuse to accept the resulting judgment before filing any de novo civil action in state or federal court.") However, the fact that the Act allows for a "de novo" civil action is not at odds with a finding that this Court does not sit as an alternate forum for an appeal on the question of a Vaccine Court petition's timeliness. A civil action under the statute is "de novo" not in the sense that it is a second bite at the same apple but because it is an entirely separate process in which different claims (under state torts law) are asserted. Indeed, the Vaccine Court proceeding is not a civil action at all, but is instead a compensation process governed by rules intended to (when possible) avoid fundamental elements of tort law such as proof of causation in favor of a faster, more certain recovery for those unfortunately injured by otherwise highly beneficial vaccines.

Thus, the filing of a civil action does not mean that the courts in which such actions are filed may review the timeliness of the earlier, different Vaccine Court compensation program

⁵ Plaintiffs themselves emphasize this distinction in their argument, pointing out that the Vaccine Program Special Masters only determine compensation entitlement under the Program rather than whether a plaintiff is entitled to recover damages under the traditional tort system. *See* Doc. No. 153 at 5.

proceedings "de novo." Quite to the contrary, the Vaccine Act requires that the proceedings in the civil action and the Vaccine Court be kept separate, to the extent they might overlap substantively. See 42 U.S.C. § 300aa-23(e) (at trial in a civil action, "the Vaccine Injury Table, any finding of fact or conclusion of law of the United States Court of Federal Claims or a special master in a proceeding on a petition filed under section 300aa-11 of this title and the final judgment of the United States Court of Federal Claims and subsequent appellate review on such a petition shall not be admissible."). Therefore, it is the role of the Vaccine Court and its reviewing courts to determine the timeliness of petitions filed in that proceeding. Where, as here, the timeliness of Plaintiffs' petitions was raised, considered and decided in the Vaccine Court, 8 this Court will not

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⁶ Indeed, if the proceedings in the Vaccine Court and any subsequent civil action were considered to be part of a single proceeding then the "law of the case" doctrine would dictate that this Court follow the ruling of the Vaccine Court as to its legal determination that the Plaintiffs' petitions were untimely. "As most commonly defined, the doctrine [of the law of the case] posits that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case." *Arizona v. California*, 460 U.S. 605, 618 (1983). And, the rule applies to the decisions of a coordinate court in the same case. *See Snyder's-Lance, Inc. v. Frito-Lay N. Am., Inc.*, 991 F.3d 512, 522 (4th Cir. 2021) ("it is not unheard of for one appellate court to need to apply another's prior decision as the law of the case. *E.g., Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 816 (1988) (noting, in a case involving decisions by both the Seventh and Federal Circuits, that the law of the case "doctrine applies as much to the decisions of a coordinate court in the same case as to a court's own decisions," and collecting cases")).

⁷ Plaintiffs argue that the reference in this provision to "any stage of a civil action" supports their contention that the Court ought not consider the Vaccine Court's earlier ruling on timeliness. The Court disagrees. In the specific context of this provision – the *trial* of the civil action – the reference to "stages" refers to the earlier part of the same section in which the statute says that "a civil action against a vaccine manufacturer … shall be tried in three stages ("liability," "general damages" and "punitive damages")." 42 U.S.C. § 300aa-23(a)-(d). Accordingly, this statutory language simply means that the earlier proceedings in the Vaccine Court may not be used to prove liability or either type of damages.

⁸ While a Vaccine Court petitioner may appeal the ruling of a Special Master on the timeliness of a petition to the Court of Federal Claims and the Federal Circuit, the absence of such appeal(s) does not impact whether or not this Court may decide what is in effect an appeal of that decision. This Court need not and does not reach the different question of whether a third party might raise

reconsider that ruling in deciding whether the threshold statutory requirement of a timely Vaccine Court petition has been satisfied.

Also, the Court finds Plaintiffs' proposal for this Court to determine the timeliness of a Vaccine Court petition anew based on the different law of the Fourth Circuit and/or North Carolina law would invite (and almost guarantee) inconsistent rulings on the application of the Vaccine Act's procedural limitations period to similarly situated petitioners. The Vaccine Act is a federal statute that applies to plaintiffs from every state. If the timeliness of each Vaccine Court petition ultimately turned on the vagaries of the different federal circuit or state law applicable where a Vaccine Court petitioner decided to file a subsequent civil action then two petitioners who received the same vaccine and suffered the same alleged injury at the same time might well be treated differently. Further, the initial determination of timeliness in the Vaccine Court and the later appeal of that decision would be decided under different law. The Act does not in any way suggest that whether a petitioner can file a subsequent civil action should be decided in such an inconsistent and inequitable manner.⁹

Finally, the Court must consider that if it did reverse the Vaccine Court on the issue of the timeliness of Plaintiffs' Vaccine Court petitions, there is no provision in the Vaccine Act that would allow this Court to remand the Plaintiffs' claims back to the Vaccine Court so that they could be considered on the merits in the compensation Program. As discussed above, Congress clearly intended that while the civil tort system might ultimately be available, the Vaccine Court

the timeliness of a plaintiff's Vaccine Court petition if that issue was not specifically considered at the Vaccine Court.

⁹ The fact that petitioners who take the same vaccine might have different results in prosecuting their substantive state tort law claims does not imply otherwise. Again, the civil action process is simply a different process and plaintiffs pursuing similar claims in various state or federal courts with different results is not uncommon (although the structure of the MDL seeks to make it somewhat less likely).

would be a meaningful – and mandatory – Program that would assess the merits of a vaccine injury claim in the first instance. Unlike a direct appeal to the Court of Federal Claims or the Federal Circuit, where a successful challenge to a finding of untimeliness would be followed by a return to the Vaccine Court for consideration of the merits, a finding in this Court that the Plaintiffs' Vaccine Court petitions were in fact timely would not lead to a remand but rather would result in entirely bypassing an opportunity to consider the merits in the Vaccine Court. This is contrary to the plain language and obvious intent of the Act, which, again, makes the Vaccine Court a required first step in pursuing a vaccine injury claim.

In sum, the Court finds that it may not and should not reconsider the determination of the Vaccine Court that Plaintiffs' petitions in that proceeding were untimely. Because the timely filing of a Vaccine Court petition is required to file a civil action in this Court, Defendants motion to dismiss must be granted and these Plaintiffs' claims dismissed.¹⁰

Further, even if this Court could properly determine the timeliness of a Vaccine Court petition under our governing law, it would find that these Plaintiffs' petitions were not timely filed in the Vaccine Court. First, Plaintiffs urge the Court to find their petitions timely through the application of a "discovery rule," which would not begin the period of limitations until the date when they each actually learned of the alleged connection between their alleged injuries and their Gardasil vaccinations. However, the "discovery rule" does not apply to the Vaccine Act. As

¹⁰ Merck has moved in the alternative to dismiss Plaintiffs' claims based on a lack of subject matter jurisdiction (Rule 12(b)(1)) and for failing to state a claim (Rule 12(b)(6)). Because the petition must be dismissed in accordance with the statute, the Court need not decide whether the dismissal should proceed under Rule 12(b)(1) or (6) or both.

¹¹ At oral argument, Plaintiffs acknowledged that they were aware of the authority holding that a "discovery rule" did not apply. However, they did not abandon their contention that this Court should find that a "discovery rule" should be created for Vaccine Act claims.

explained in detail in *Cloer v. Sec'y of Health & Hum. Servs*, Congress considered but chose not to include a "discovery rule" in the Vaccine Act and the text and structure of the Act make clear that a "discovery rule" should not be implied. 654 F.3d 1322, 1336–40 (Fed. Cir. 2011). Plaintiffs have cited to no Vaccine Act case in which a "discovery rule" was applied, and the Court declines to create one in this MDL. Therefore, as acknowledged by Plaintiffs, their petitions were untimely in the absence of a discovery rule.

Unlike the "discovery rule," the Federal Circuit has held that the time for filing a petition in Vaccine Court may be "equitably tolled." *See Cloer*, 654 F.3d at 1344. Courts in the Fourth Circuit engage in a "case-by-case examination to determine if an equitable tolling of the filing period is appropriate." *Dyson v. Henrico Cnty. Sch. Bd.*, No. 3:20CV547, 2020 WL 7398836, at *4 (E.D. Va. Dec. 16, 2020). The doctrine of equitable tolling is to be employed "sparingly." *Irwin v. Dep't of Veteran's Affairs*, 498 U.S. 89, 96 (1990) *Irwin*, 498 U.S. at 96. "Equitable tolling has long been considered an extraordinary remedy in this circuit, and litigants face a considerable burden to demonstrate that it applies." *Hazlegrove v. Colonial Pipeline Co.*, No. 3:18cv284, 2018 WL 6683030, at *4 (E.D. Va. Dec. 19, 2018) (citing *CVLR Performance Horses, Inc. v. Wynne*, 792 F.3d 469, 476 (4th Cir. 2015)).

Equitable tolling requires plaintiffs to show "two elements": diligence and extraordinary circumstances. *Menominee Indian Tribe of Wisc. v. United States*, 577 U.S. 250, 255 (2016). For equitable tolling to apply, the plaintiff must show: "(1) extraordinary circumstances, (2) beyond [her or] his control or external to [her or] his own conduct, (3) that prevented [her or] him from filing on time." *United States v. Sosa*, 364 F.3d 507, 512 (4th Cir. 2004). The Supreme Court has cautioned against the expanded use of the equitable tolling doctrine, stating that "[i]n the long run, experience teaches that strict adherence to the procedural requirements specified by the legislature

is the best guarantee of evenhanded administration of the law." *Baldwin Cnty. Welcome Ctr. v. Brown*, 466 U.S. 147, 152 (1984) (citation and quotation marks omitted).

Based on the allegations in the Plaintiffs' Complaints as well as matters of which the Court may take judicial notice (including the decisions of the Vaccine Court and the Complaints of the other Plaintiffs in the MDL), it is clear that Plaintiffs are not entitled to have the period of limitations equitably tolled. And, no further evidentiary development is required for the Court to determine that equitable tolling does not apply. *See Fluharty v. City of Clarksburg*, 2015 WL 2341727, at *4 (N.D.W.V. May 14, 2015). To dismiss a claim as time-barred at the motion to dismiss stage, the moving defendant must show both (1) that a breach of the applicable limitations provision is shown on the face of the complaint, and (2) "that the plaintiff's potential rejoinder to the affirmative defense [is] foreclosed by the allegations in the complaint." *Goodman v. Praxair, Inc.*, 494 F.3d 458, 466 (4th Cir. 2007).

As described above, and acknowledged by Plaintiffs at oral argument, in the absence of equitable tolling, Plaintiffs' petitions in the Vaccine Court were untimely. Further, none of the plaintiffs have alleged any individualized circumstances which might establish the extraordinary circumstances required for equitable tolling. Rather, they have all asserted the same facts alleged by numerous other Plaintiffs who were demonstrably able to timely file petitions in the Vaccine Court. Indeed, much of their "equitable tolling" argument is just a repackaging of their "discovery rule" arguments. ¹² See Cloer, 654 F.3d at 1344 ("Dr. Cloer individually asks for the same relief [the discovery rule] as a matter of equity that Congress has withheld from all petitioners as a matter

¹² Also, Plaintiffs' contention that they were "diligent" and could not have discovered their claims until 2023 is belied by their allegations that "the medical literature has documented" the risks they allege since 2009. (*See*, *e.g.*, Needham Compl. ¶ 355).

of law. But we find no basis in equity for doing so."). Therefore, it is unnecessary to wait until

discovery has ended to find the absence of equitable tolling based on Plaintiffs' non-personalized

allegations of "fraud" and "concealment" (which, again, did not deter numerous other Plaintiffs

from filing timely petitions). In sum, even if the Court were empowered to decide the issue of

"equitable tolling" de novo, it would reach the same conclusion that these Plaintiffs' Vaccine Court

petitions were untimely and dismiss their claims on that basis.

III. ORDER

NOW THEREFORE IT IS ORDERED THAT:

1. Defendants' Motions to Dismiss (Doc. Nos. 141, 144) are **GRANTED**; and

2. Plaintiffs Needham, Roman, Walker and Nielson's claims are **DISMISSED**.

SO ORDERED ADJUDGED AND DECREED.

Signed: July 31, 2024

Kenneth D. Bell

United States District Judge